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EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,464	MEYER ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-101* is/are pending in the application.

4a) Of the above claim(s) *67-74,79-86 and 93-99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-66,75-78,87-92,100 and 101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed December 23, 2002. Currently, claims 63-101 are pending. Claims 67-74, 79-86, 93-99 have been withdrawn as drawn to non-elected subject matter. Claims 63-66, 75-78, 87-92, 100-101 have been examined to the extend that the read on the elected invention.

Election/Restrictions

2. Applicant's election of Group I and SEQ ID NO: 39 (polymorphism cadpk17) in Paper filed December 23, 2002 is acknowledged. Applicant traversed to the restriction requirement. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Applicants traverse the restriction to a single polymorphic sequence. The response argues that the polymorphisms are related by at least one common inventive concept. Applicant argue that each of these sequences is to an allelic variant of a common gene, CADPKL. Further Applicant argues that each of these variants correlates with a neuropsychiatric disorder. First, whether claims are related by a common inventive concept does not demonstrate that the subject matter is not patentabley distinct, could support separate patents or require a burden of search. Second, Applicants have not shown that each of these variants is associated with neuropsychiatric disorder. As seen in Figure 5 and 7, Applicants do not appear to have tested the polymorphisms let alone shown an association. Further, many of the SNPs

have only been shown to have a p>0.05. This statement encompasses p-values of 0.06, 0.5 and even 1.0 which are not indicative of an association with a disease.

Even in the event that applicant's were able to show that each of these SNPs were associated with the general class of diseases such as neuropsychiatric disorders, the nucleic acids have been considered independent and distinct by the examiner since there is no indication the nucleic acids are obvious over one another. As stated in the office action, "Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions." Applicants do not appear to have made such a statement, thus applicants have not overcome prima facie case for distinctness. Distinctness can be shown where inventions are related. It is evident from the patent literature that multiple mutations and allelic variants are associated with neuropshyciatric disorders, including schizophrenia and biopolar disorder. The showing that these mutations are all associated with the same disease does not render the nucleic acids obvious over one another. Similarly, in the instant application, since there is no evidence of linkage disequilibrium, the presence of a point mutation in one position of the over 20,000 nucleotides would not render any other the other point mutations obvious. Each of these nucleic acids and their association to a disease would be patentable over each other such that double patenting would not be appropriate.

However, if the Applicant maintains that the nucleic acids are not distinct from one another, applicants may clearly admit on the record that this is the case such that if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a 103 rejection of the other inventions.

Claims 67-74, 79-86, 93-99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Priority

4. This application claims priority as a continuation-in-part of U.S. Serial No. 09/757,300, filed on January 9, 2001.

Drawings

5. The drawings are acceptable.

Specification

6. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

7. Claim 101 is objected to because of the following informalities.

Claim 101 recites "nucleotide sequent." It is presumed the recitation should read "nucleotide sequence." Appropriate correction is required.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 63-66, 75-78, 87-92, 100-101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to isolated nucleic acids which comprise a nucleotide sequence of a polymorphic region of a CAPKL allelic variant where the variant has a nucleotide sequence which differs from a reference sequence wherein said variant is indicative of a neuropsychiatric disorder.

Neither the specification nor the art teaches how to make and use the invention as broadly as claimed. It would require undue experimentation for the skilled artisan to determine how to use the claimed nucleic acids.

The specification teaches that the Calcium/Calmodulin dependent protein kinase like gene, CADPKL, is from Genbank. The specification further teaches that Calcium/Clamodulin protein kinases play important roles in a variety of intracellular signaling cascades, including CAMK1. The specification provides an alignment

between CADPKL and CAMK1 (Figure 1). The specification teaches that the amino acid residues in italicized font correspond to consensus sequences that are largely conserved across the serine/threonine and tyrosine protein kinase superfamilies, such that the specification concludes that the CADPKL is a protein kinase. The specification continues to state that "there is at best only come indirect evidence, from expression patterns and sequence homologies, indicating that CADPKL might play a role in the formation and/or organization of the human brain, and/or in cell signaling processes within the human brain. However, there is currently no direct evidence known in the art to directly linked CADPKL with abnormal neurological activity. In particular, there is no data suggesting that CADPKL may be involved or associated with abnormal neurological activity such as a neuropsychiartric disorder (page 4). The specification teaches that the polymorphism cadpk17 (SEQ ID NO: 39) was found to have a p> 0.0213 (Table 5). The specification teaches that the populations which were studied were phenotypic for a neuropsychiatric disorder (e.g. schizophrenia)(page 96).

It is noted that the response has listed a sequence which is known in the prior art and which has a high percentage sequence similarity to a claimed sequence. Absent factual evidence, a percentage sequence similarity of less than 100% to the entire sequence is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of

these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over biomolecules of related function upon a significant amount of further research.

The specification asserts that the polymorphism cadpk17 is associated with neuropsychiatric disorders. Neurospychiatric disorders is a very large class of disorders which includes schizophrenia, schizoaffective disorder, bipolar disorder, unipolar affective disorder and adolescent conduct disorder, for example. The specification has not provided analysis of bipolar disorder and any variant such that there is a predictable outcome. The populations which were studied were stated to contain individuals who are phenotypic for a neurophsychiatric disorder such as schizophrenia. There is no indication that the populations contain any other diseases. It is unclear what the composition of the populations were comprised of. A sample of all schizophrenic individuals would not be suggestive that the polymorphism was associated with bipolar disorder since these two diseases are genetically distinguishable. Further, if the population contained some bipolar individuals, but the polymorphism was not detected in any of these individuals, the skilled artisan would be required to perform undue experimentation to determine how to use this information and whether the information is

useful at all in detecting a person at risk for a neuropsychiatric disorder. Since it is unclear from the speciation what the claimed SNP has been correlated with to obtain a p value of 0.0213, the skilled artisan would not know how to use the polynucleotide. It is unpredictable whether the polynucleotides are correlated with any neurosychiatric disorder, without further experimentation.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 63-66, 75-78, 87-92, 100-101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its ~~ennoblement~~ enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written

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description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of specifies have been described by their complete structure. In the instant case, Applicant has 20 SNPs and 9 microsatellite repeats.

The essential elements of the claims are drawn to isolated nucleic acids which comprise a nucleotide sequence of a polymorphic region of a CAPKL allelic variant where the variant has a nucleotide sequence which differs from a reference sequence. The claims encompass SNPs, deletions, insertions, microsatellite repeats, among other allelic variants.

There is not adequate description of the genus of isolated nucleic acids which comprise a nucleotide sequence of a polymorphic region of a CAPKL allelic variant where the variant has a nucleotide sequence which differs from a reference sequence. The specification only discloses 29 variants within the scope of the genus: isolated nucleic acids which comprise a nucleotide sequence of a polymorphic region of a CAPKL allelic variant where the variant has a nucleotide sequence which differs from a reference sequence. The 29 variants described are not representative of the genus of

isolated nucleic acids which comprise a nucleotide sequence of a polymorphic region of a CAPKL allelic variant where the variant has a nucleotide sequence which differs from a reference sequence. There is substantial variability among the species of nucleic acids encompassed in the scope of the claim because only 29 specific mutations have been identified in the gene with 10 exons which spans 148Kb. The art teaches that the most common variations are single nucleotide polymorphisms (SNPs) which occur approximately once every 100 to 300 bases. Given this rule, one would expect between 500-1500 SNPs. This is only one type of variation. The 20 SNPs described in the instant specification would not be representative of these 500-1500 SNPs. The specification has also not defined a structural feature of the variants which would be common to all members of the genus that constitutes a substantial portion of the genus. Furthermore, one of skill in the art would conclude that applicant was not in possession of the claimed "isolated nucleic acids which comprise a nucleotide sequence of a polymorphic region of a CAPKL allelic variant where the variant has a nucleotide sequence which differs from a reference sequence" because the description of only 29 members of this genus is not representative of the variants of the genus and is insufficient to support the claims. Thus, the specification does not adequately provide a written description for isolated nucleic acids which comprise a nucleotide sequence of a polymorphic region of a CAPKL allelic variant where the variant has a nucleotide sequence which differs from a reference sequence.

With respect to claims drawn more specifically to nucleic acids comprising SEQ ID NO: 39, SEQ ID NO: 12 and SEQ ID NO: 13, the claim encompass a large genus of

nucleic acids which have not been adequately described. Nucleic acids which minimally contain these smaller sequences read on any homologue, splice variant, orthologue, truncated or variant sequence. The specification has only described these sequences embedded within a single genomic/cDNA sequence. The art teaches SEQ ID NO: 12 embedded within a mouse chromosome clone. The instant specification has not described a mouse CADPKL gene or sequence comprising SEQ ID NO: 12 (see for example Genbank Accession Number AC122914, May 2002). Moreover, Yoganathan teaches a CAMK-X1 gene which comprises SEQ ID NO: 39 which is a variant of SEQ ID NO: 1, 2, 4 which is not described by the instant specification. Weighing all factors 1) partial structure of the DNAs that comprise SEQ ID NO: 12, 13, 39, 2) the breadth of the claims as reading on genes yet to be discovered in both humans and other animals 3) the lack of correlation between the structure and the function of the genes; in view of the level of knowledge and skill in the art, one skilled in the art would not recognized from the disclosure that the applicant was in possession of the genus of DNAs which comprise SEQ ID NO: 12, 13, 39.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 63-64, 75-76, 87-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 63-64, 75-76 are indefinite over the recitation "isolated nucleic acids which comprise a nucleotide sequence of a polymorphic region of a CADPKL allelic variant where the variant has a nucleotide sequence which differs from a reference sequence" because it is unclear whether the claim reads on every nucleic acid with a polymorphism of CADPKL. The claims appear to require a polymorphic variant, namely G, within a larger sequence. The claim does not appear to require that the sequence has any functional or structural limitations except containing a allelic variant. The variant is the single nucleotide position which differs between SEQ ID NO: 1, 2 or 4.

B) Claims 87-88 are indefinite because the claim appears to claim two elements using (a) and (b) however, it appears as though these two elements are identical. In the event that the probe which specifically hybridizes and the probe which comprises SEQ ID NO: 39 are the same probe, appropriate correction is required. Alternatively, it is unclear whether the claim requires two probes. Similarly, Claims 89 is unclear whether the kit requires to primers or whether the second clause is used to modify the single primer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Pat. 5,474,796, December 1995).

Claims 63-64 are broadly drawn to any nucleic acid which comprises a polymorphic region of a CADPKL nucleic acid, which nucleic acid has a reference sequence selected from SEQ ID NO: 1, 2, 4. The polymorphic region of SEQ ID NO: 39, for example if "g." The claim does not require any length limitation for the polymorphic region, in fact Claim 64 states that the polymorphic region comprises a SNP (i.e. a single nucleotide), nor does the claim require any particular flanking sequences. Therefore, reading the claims broadly, the claims are drawn to any nucleic acid comprising a "g."

Brennan teaches an array which contains oligonucleotides having 10 nucleotides each (10-mers). Every possible permutation of the 10-mer oligonucleotides is represented on the array (col. 9). Therefore, Brennan anticipates the claimed invention as broadly as claimed.

12. Claims 63-66, 100-101 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (Genbank Accession Number AQ077073, August 20, 1998).

Adams teaches a nucleic acid genomic clone which comprises SEQ ID NO: 39. Nucleotides 1-21 of SEQ ID NO: **39** are 100% identical with nucleotides 360-380 of the human clone taught by Adams (limitations of Claims 63-66).

The nucleic acid of Adams also comprising SEQ ID NO: 12. Nucleotides 1-8 of SEQ ID NO: **12** are 100% identical with nucleotides 271-288 of Adams (limitations of Claims 100-101).

Therefore, the instant claimed invention is anticipated by the nucleic acid taught by Adams.

13. Claims 100-101 are rejected under 35 U.S.C. 102(b) as being anticipated by NCI-CGAP (Genbank Accession Number AI215131, October 1998).

NCI-CGAP teaches a nucleic acid from a homo sapiens cDNA clone which comprises SEQ ID NO: 12. Nucleotides 1-18 of SEQ ID NO: **12** are 100% identical with nucleotides 233-250 of the NCI-CGAP cDNA clone (limitations of Claims 100-101). Therefore, NCI-CGAP teaches every limitation of the claimed invention.

14. Claims 100-101 are rejected under 35 U.S.C. 102(b) as being anticipated by Grafham (Genbnak Accession Number HS272L16, November 1999).

Grafham teaches a nucleic acid DNA sequence from chromosome 1q32.1-32.3 which comprises SEQ ID NO: 12 and SEQ ID NO: 13. Nucleotides 1-18 of SEQ ID NO: **12** are 100% identical with nucleotides 143,358-143,375 of the nucleic acid taught by Grafham. Nucleotides 1-21 of SEQ ID NO: **13** are 100% identical with nucleotides 143,687-143,667 of Grafham. Therefore, Grafham teaches every limitation of the claimed invention.

15. Claims 63-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Yoganathan et al. (WO 02/24947 A2, International Publication Date March 28, 2002; International filing Date September 20, 2001; Published in English; Priority Date September 20, 2000).

Yoganathan et al. (herein referred to as Yoganathan) teaches a calmodulin kinase which encodes CaMK-X1 which maps to chromosome 1q32.1-32.3. The nucleic acid sequence is shown in SEQ ID NO: 3. Nucleotides 1-21 of SEQ ID NO: **39** are 100% identical to nucleotides 713-733 of the CaMK-X1 sequence of Yoganathan (limitations of claims 63-66). Therefore, Yoganathan anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 75-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US Pat. 5,474,796, December 1995) in view of Ahern (The Scientist, Vol 9, No. 5, pages 20, July 1995).

This rejection is drawn to a broad kit which may comprise any number of probes and primers and instructions, not SEQ ID NO: 39 or a probe/primers which specifically detects cadpk17 mutation in CADPKL.

However, It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, it is noted that kit does not contain any structural limitations such that the components must be in a box or packaged together.

Brennan teaches an array which contains oligonucleotides having 10 nucleotides each (10-mers). Every possible permutation of the 10-mer oligonucleotides is represented on the array (col. 9).

Brennan does not specifically teach packaging the array and instructions in to a kit.

Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already comes prepared.

Therefore, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings Brennan with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. The ordinary artisan would have been motivated to have packaged the array of Brennan into a kit, as taught by Ahern for the express purpose of saving time and money.

18. Claims 75-78, 87-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US Pat. 5,474,796, December 1995) in view Adams et al. (Genbank Accession Number AQ077073, August 20, 1998).

This rejection is drawn to a broad kit which may comprise any number of probes and primers and instructions, not SEQ ID NO: 39 or a probe/primers which specifically detects cadpk17 mutation in CADPKL.

However, It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, it is noted that kit does not contain any structural limitations such that the components must be in a box or packaged together.

Adams teaches a nucleic acid genomic clone which comprises SEQ ID NO: 39. Nucleotides 1-21 of SEQ ID NO: **39** are 100% identical with nucleotides 360-380 of the human clone taught by Adams (limitations of Claims 63-66). The nucleic acid of Adams may be used as a probe and will hybridize to the polymorphic region of CADPKL.

Adams does not specifically teach packaging the array and instructions in to a kit.

Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already comes prepared.

Therefore, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings Adams with the teachings of Ahern to incorporate the clone into a packaged kit. The ordinary artisan would have been motivated to have packaged the nucleic acid clone of Adams into a kit, as taught by Ahern for the express purpose of saving time and money. Kits allow for further analysis and studying of nucleic acids.

Conclusion

19. No claims allowable.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
June 2, 2003

Jehanne Souaya

JEHANNE SOUAYA
PATENT EXAMINER
6/3/03